

Review Date: _____

**Additional DHHS Protections Pertaining to Research, Development, and
Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro
Fertilization**

Checklist for Protocol # _____

The purpose of this checklist is to aid you in your evaluation of CDC research involving fetuses, pregnant women, and human in vitro fertilization. In addition to the responsibilities of the IRB under Subpart A, the IRB shall carry out the following *additional duties* when research involves fetuses, pregnant women, and human in vitro fertilization. However, if pregnant women and fetuses are *NOT* the target of the research, Subpart B does not apply.

Minimal Risk

The Federal Regulations divide research into that which is minimal or not greater than minimal risk to the participant and that which is greater than minimal risk. The definition of minimal risk given in §46.102(i) reads as follows:

“Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Level of Risk for this protocol (please insert “minimal” or “greater than minimal”):

Please use the following determination key when evaluating research involving fetuses, pregnant women, and human in vitro fertilization to ensure that the **additional safeguard** has been satisfactorily addressed:

- Y** = adequately addressed in protocol
M = missing in protocol
I = incomplete or problematic in protocol

Additional Safeguard	45 CFR 46 Subpart “B” § 46.205	Notes
<i>Selection</i>	“determine that adequate consideration has been given to the manner in which potential subjects will be selected...”	
<i>Informed Consent</i>	“...adequate provision has been made...for monitoring the actual informed consent process. For example:	
	“overseeing the actual process by which individual consents required ...are secured either by approving induction of each individual ...or verify...that approved procedures for induction...are being followed...”	
	“monitoring the progress...and intervening as necessary through such steps as visits to the ...site and continuing evaluation to determine if any unanticipated risks have arisen...”	
<i>Animal Studies</i>	“...appropriate studies on animals and nonpregnant individuals have been completed.”	
<i>Risk</i>	“except where the purpose...is to meet the health needs of the mother or...fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives...”	
<i>Pregnancy Termination/Fetal Viability</i>	“individuals engaged...will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy...”	
	“individuals engaged...will have no part in determining the viability of the fetus at the termination of the pregnancy; and...”	
	“no procedural changes which may cause greater than minimal risk to the fetus or the pregnant women will be introduced...for terminating the pregnancy solely in the interest of the activity,	
	“No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of this activity..”	

Activities directed toward pregnant women as subjects:

Additional Safeguard	§ 46.207	Notes
<i>Purpose</i>	“...is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or...	
<i>Risk</i>	the risk to the fetus is minimal.”	
<i>Competency</i>	“...the mother and father are legally competent and...	
<i>Informed Consent</i>	have given their informed consent after having been fully informed regarding possible impact on the fetus (both mother’s and father’s signature blocks), except...	
<i>Provisions if Father’s Signature Not Secured</i>	“...the father’s informed consent need not be secured if: (1) the purpose...is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape”.	

Activities directed toward fetuses in utero as subjects:

Additional Safeguard	§ 46.208	Notes
<i>Purpose</i>	“...is to meet the health needs of the particular fetus and...	
<i>Risk</i>	...the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or	
	the risk to the fetus imposed by the research is minimal and the purpose...is the development of important biomedical knowledge which cannot be obtained by other means.”	
<i>Competency</i>	“...the mother and father are legally competent and...	
<i>Informed Consent</i>	have given their informed consent after having been fully informed regarding possible impact on the fetus (both mother’s and father’s signature blocks), except...	
<i>Provisions if Father’s Signature Not Secured</i>	“...the father’s informed consent need not be secured if: (1) the purpose...is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape”.	